

REMARKS

Claims 1-2, 4-14, and 16-19 are pending with claims 16-19 added by this paper.

Perfecting the priority date to the filing date of German Application No. 19843254.2

Applicants submit herewith a verified English translation of the German priority document filed September 10, 1998, to perfect their priority date.

Claim Rejections Under 35 USC §112 and §101

Claims 1-15 stand rejected for allegedly being indefinite and claims 12 and 15 stand rejected for reciting a use without setting forth any steps involved in the process. With respect to the indefiniteness rejections, Applicants have amended the claims to use open terminology, such as comprising or made from, deleted narrower ranges from claims 8 and 10 and presented them in dependent claims, deleted the trademarks from claim 10, deleted the term "special" from claim 11, rewrote claim 12, and canceled claim 15. Applicants respectfully submit that these amendments do not narrow the scope of the claims.

With respect to the allegation that "at least one other polymer" in claim 5 is indefinite, Applicants have amended claim 5 to clarify that the coating comprises a polycyanoacrylic acid ester polymer and at least one other polymer. Applicants respectfully submit that one of skill in the art would readily understand that the coating can comprise an additional polymer, and would readily understand that other polymers may exist in a coating. Consequently, Applicants respectfully submit that this claim can be understood with respect to its metes and bounds by one skilled in the art. Thus, Applicants respectfully submit that this rejection should be withdrawn in view of twice amended claim 5.

Claim Rejections Under 35 §102

(Radiance and Tam Patents)

Claims 1-3, 5, 8, and 12-14 stand rejected as allegedly being anticipated by U.S. Patent No. 6,261,320 (Radiance) or U.S. Patent No. 6,287,249 (Tam). Applicants respectfully traverse

these rejections.

The Radiance patent filed February 19, 1999, is a continuation-in-part of Application No. 08/975,584, filed on November 21, 1997, now U.S. Patent No. 6,120,535 (McDonald). As stated above, Applicants have perfected their priority date of September 10, 1998. This predates the filing date of the Radiance patent of February 19, 1999. Although the Radiance patent discloses various coatings including cyanoacrylates (col. 22, line 61- col. 23, line 23), the McDonald patent fails to include such a disclosure. Consequently, even if the Radiance patent can rely on McDonald's priority date, the failure to include this disclosure renders the Examiner's reliance on the McDonald's patent filing date untenable. Consequently, Applicants respectfully submit that the rejections with respect to this reference should be withdrawn.

With respect to the Tam patent, Tam discloses a radiation delivery source including a substrate layer and an outer coating layer (see col. 3, line 62 - col. 4, line 7). In one embodiment depicted in the drawings, the substrate layer is a thin film layer, which may be attached to or which comprises a portion of the inflatable balloon (see col. 4, lines 33-36 and Fig. 4). Although Tam defines that the source can further comprise a stent carried by the balloon (claim 15), and further discloses various coating materials for the radioactive sources (col. 20, line 32 - col. 21-23), Tam does not disclose coating a stent. Rather, Tam discloses coating a substrate attached to a balloon and positioning a stent on the balloon prior to implantation (col. 5, lines 31-34). Consequently, Tam cannot anticipate the claimed invention.

Goldstein

Claims 1-5, 8-10, and 12-14 stand rejected as allegedly being anticipated by U.S. Patent No. 6,143,037 (Goldstein). Goldstein discloses over 20 medical devices, including intravascular stents, that may be coated by various compositions and methods (column 31, lines 25-48). Goldstein also discloses polymers useful in the invention, such as polyesters, polyethers, polyisocynoacrylates, polyacrylamides, poly(orthoesters), polyphosphazenes, polypeptides, polyurethanes, and mixtures thereof (col. 14, line 64 - col. 15, line 10).

However, a generic disclosure encompassing vast numbers of embodiments does not describe, and thus anticipate, all embodiments embraced therein merely because they're within

the scope of the disclosure. See *In re Ruschig* 145 USPQ 274 (CCPA 1965). In this case, Goldstein prefers medical devices such as sutures (col. 31, lines 49-63), exemplifies coating sutures, screws, and ceramic particles. See, cols. 32-35. Goldstein fails to provide any preferences or examples of a stent comprising a coating where the coating comprises a polymer or a polymer mixture, which in turn comprises or is made from a polycyanoacrylic acid ester or a polymethylene malonic acid ester, or a mixture thereof. Consequently, out of the vast numbers of polymers that may be chosen to coat a variety of medical devices, Goldstein fails to provide any guideposts or blazemarks for one of skill in the art to pick out a specific combination to anticipate Applicants' invention. Consequently, Applicants respectfully submit that these rejections should be withdrawn. See *In re Baird*, 16 F.3d 380, 29 USPQ2d 1550 (Fed. Cir. 1994).

Clark

Claims 1-2, 4-8 and 11-12 stand rejected as allegedly being anticipated by U.S. Patent No. 6,143,352 (Clark). Applicants have amended claim 1 to include the substantive features of canceled claim 3. Consequently, Applicants respectfully submit that these rejections should be withdrawn.

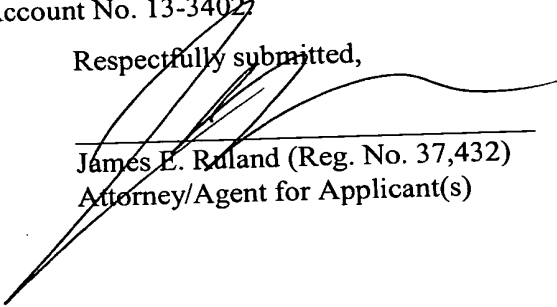
Claim Rejections Under 35 USC §103

Claim 15 stand rejected as allegedly being unpatentable over Goldstein in view of Clark. Applicants have canceled claim 15. Consequently, Applicants respectfully submit that this rejection is no longer applicable to claim 15.

In view of the above remarks, favorable reconsideration is courteously requested. Attached hereto is a marked-up version of the changes made to the claims by the current Amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE." If there are any remaining issues which can be expedited a telephone conference, the Examiner is courteously invited to telephone counsel at the telephone number indicated below.

The Commissioner is hereby authorized to charge any fees associated with this response or credit any overpayment to Deposit Account No. 13-34027

Respectfully submitted,


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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE CLAIMS

Claims 3 and 15 have been canceled.

Claims 1-2 and 4-14 have been amended as follows.

1. (Amended) ~~Medical implants that consist of a vehicle~~ A stent comprising a coating
~~which that is coated with a polymer or a polymer mixture, characterized in that the polymer~~
~~mixture contains~~ comprises a polycyanoacrylic acid ester, or a polymethylene malonic acid ester,
or a mixture thereof.

2. (Amended) ~~Medical implants~~ A stent according to claim 1, wherein the stent
comprises a vehicle ~~consists of~~ metal or a polymer.

4. (Twice Amended) ~~Medical implants~~ A stent according to claim 1, wherein the coating
comprises a cyanoacrylate butyl ester.

5. (Twice Amended) ~~Medical implants~~ A stent according to claim 1, wherein the coating
~~consists of~~ comprises a polycyanoacrylic acid ester polymer and at least one other polymer.

6. (Amended) ~~Medical implants~~ A stent according to claim 5, wherein substances that
influence the degradation of the polymer are contained in the polymer coating.

7. (Amended) ~~Medical implants~~ A stent according to claim 6, wherein the coating
further comprises calcium carbonate.

8. (Amended) ~~Medical implants~~ A stent according to claim 5, wherein the at least one
~~of these additional other~~ according to claim 5, wherein the at least one ~~of these additional other~~
polymers ~~originates~~ is made from ~~one of the substance groups that are indicated below:~~ a proteins
(especially albumin, gelatin, fibrinogen, fibrin, hirudin, heparin, collagen or immunoglobulin) as

well as or a derivatives thereof, (~~especially crosslinked polypeptides, conjugates of proteins with polyethylene glycols and other polymers~~), a pseudopolyamino acids, a starch or a starch derivatives, a chitin, a chitosan, a pectin, a polylactic acid, a polyglycolic acid, a polyhydroxybutyric acid, a polyester, a polycarbonates, a polyamides, a polyphosphazenes, a polyvinyl alcohol, a polyamino acids, a poly- ξ -caprolactone, a polyorthoester, a polyurethane, a polyurea, a polyethylene terephthalate, ~~and~~ or a polymethylene malonic acid ester.

9. (Amended) ~~Medical implants~~ A stent according to claim 5, wherein the coating polymer layer that is applied contains comprises at least one softener.

10. (Amended) ~~Medical implants~~ A stent according to claim 9, wherein the softener is a nonionic surfactant, ~~especially nonylphenoxy polyethylene oxide (Synperonic NP20), octoxynol (Triton X-100) or poloxamers (Pluronic F127 or Pluronic F68).~~

11. (Twice Amended) A Sterile sterile solution of a polymer mixture in ~~a special~~ an incubation vessel for the production of ~~medical implants~~ a stent according to claim 1.

12. (Amended) ~~Use of polymers that consist of cyanoacrylates and/or methylene malonic acid esters for~~ A coating for a stent medical devices and implants, which are comprising a polymer made from a cyanoacrylate and/or a methylene malonic acid ester to prevent the proliferation of cells.

13. (Amended) A process ~~Process for producing the stent the production of medical implants according to claim 1, comprising wherein the vehicle or the medical implant that is to be coated or the part of the medical implant that is to be coated is immersed~~ immersing the stent in a solution comprising the polymer or the polymer mixture to fully or partially coat the stent, which contains the polymers that consist of cyanoacrylate and/or methylene malonic acid ester, and then drawing out the stent is drawn out from this solution.

14. (Amended) A process ~~Process~~ according to claim 13, wherein ~~in addition to the~~
~~polymers that consist of cyanoacrylate and/or methylene malonic acid ester,~~ the solution further
comprises at least one other polymers.